March 9, 2021

Dongguan Xintai Instrument Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District,
Beijing, Beijing 102401
China

Re: K202591
Trade/Device Name: Body Infrared Thermometer HT-820D
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: February 5, 2021
Received: February 10, 2021

Dear Ray Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Payal Patel
Acting Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202591

Device Name
Body Infrared Thermometer HT-820D

Indications for Use *(Describe)*
The HT-820D Body Infrared Thermometer is intended to measure human body temperature by measuring the forehead from a distance of 5-8 cm. The device can be used on people of all ages in the home and professional healthcare facilities.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K202591 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. **Date of Preparation: 03/08/2021**
2. **Sponsor Identification**

Dongguan Xintai Instrument Co., Ltd.
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3. **Designated Submission Correspondent**

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4. **Identification of Subject Device**

Trade Name: Body Infrared Thermometer
Model(s): HT-820D
Common Name: Clinical Electronic Thermometer (Infrared Thermometer)
Classification Name: Thermometer, Electronic, Clinical
Regulation Number: 21 CFR 880.2910
Product Code: FLL
Device Class: Class II

5. **Identification of Predicate Device(s)**

510(k) Number: K182597
Product Name: Infrared thermometer
Model Name: PG-IRT1602
Manufacturer: Shenzhen Pango Electronic Co., Ltd
Classification Name: Thermometer, Electronic, Clinical
Product Code: FLL

6. **Indication for Use Statement:**

The HT-820D Body Infrared Thermometer is intended to measure human body temperature by measuring the forehead from a distance of 5-8 cm. The device can be used on people of all ages in the home and professional healthcare facilities.

7. Device Description

The Infrared thermometer is an electronic thermometer using an infrared sensor to detect human body temperature by measuring forehead. The device can be used on people of all ages.

The Infrared thermometer has the following features

① Non-Contact Design.
② Quick results response time less than 1 second.
③ Memory function; Memory recall of 34 reading.
④ Switching between mute and un-mute.
⑤ Switching between Fahrenheit and Celsius.
⑥ Power management: auto power off; power display; low power reminder
⑦ Automatically power-off, if no operation for 7 seconds.
⑧ Different temperature range display different backlight, over 37.5℃ signals warning tone
⑨ Prompt for high temperature.

8. Substantially Equivalent (SE) Comparison

Item	**Subject Device(s): K202591 HT-820D Body Infrared Thermometer**	**Predicate Device: K182597 PG-IRT1602 Infrared Forehead Thermometer**	**Remark**
Classification Name	Thermometer, Electronic, Clinical	Thermometer, Electronic, Clinical	Same
Product Code	FLL	FLL	Same
Regulation Number	CFR 880.2910	CFR 880.2910	Same
Indication for Use	The HT-820D Body Infrared Thermometer is intended to measure human body temperature by measuring the forehead from a distance of 5-8 cm. The device can be used on people of all ages in the home and professional healthcare facilities.	PG-IRT1602 Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead. The device can be used on people of all ages.	Difference Analysis 1
Principle of Operation	Non-contacting, Infrared Temperature Measurement	Non-contacting, Infrared Temperature Measurement	Same
Measurement Range	34℃-43℃	34. 0℃-43.0℃	Same
Accuracy	±0.3℃	±0.2℃ at 35.0 ℃-42.0℃ Others ±0.3℃	Difference Analysis 2
Measurement distance	5~8cm	3~5cm	Difference Analysis 2
Measurement Mode	Adjusted	Adjusted	Same
Reference Body Site	Oral	Not Available	Difference Analysis 3
Operational environmental	10℃-40℃ (50°F-104°F), 15-85 %RH	Not Available	Difference Analysis 3
Storage Environmental conditions	-10℃-60℃ (50°F-140°F), 15-85 %RH	Not Available	Difference Analysis 3
Intended Use Environment	Home and Professional Healthcare Environment	Not Available	Difference Analysis 4

Display Resolution	0.1	0.1	Same
Patient Contact Materials	ABS + PC	Shell Material: ABS Lens: PMMA Button: High density polyethylene (HDPE) Color additives	Difference Analysis 5
Temperature prompts	≤37.5℃(99.5℉) Green 37.6℃-38.0℃（99.6℉-100.4℉）: Orange ≥38.1℃ (100.5℉) Red	Not Available	Difference Analysis 6
Activation	Scan button	Scan button	Same
Power requirements	Two pieces of 1.5V AA (number five) batteries	Two pieces of 1.5V AAA (number seven) batteries	Difference Analysis 4
Measurement Site	Forehead	Forehead	Same
Measuring interval	Less than 1 s	About 2 s	Difference Analysis 6
Scale selection	℃/℉	℃/℉	Same
Display screen	LCD	LCD	Same
Memory	Save last measured 34 sets memories	9 sets	Difference Analysis 6
High Temperature Prompt	Yes	Yes	Same
Back light	Yes	Yes	Same
Auto power-off	7 seconds after no operation	30 seconds after no operation	Difference Analysis 6
Sterile	No	No	Same
Single Use	No	No	Same
Size	168mm(H)*93mm(L)*46mm(w)	Not Available	Difference Analysis 2
Weight	122g	Not Available	Difference Analysis 2
Biocompatibility	ISO10993-5 ISO10993-10	ISO10993-5 ISO10993-10	Same
Electrical Safety	IEC60601-1	IEC60601-1	Same
EMC	IEC60601-1-2	IEC60601-1-2	Same
Performance	ISO 80601-2-56 ASTM E1965-98 IEC60601-1-11	ISO 80601-2-56 ASTM E1965-98	Same

The differences are included as followings:

Analysis 1:

The measurement distance and applicable user environment are identified in the Indications for Use for the subject device, while not included in that of the predicate. Both devices measure without contact, however, the subject device adds the detail of its prescribed measuring distance to its indication. The Indication for Use of the subject device also presents the intended user environment of home or health care facilities for more

clarification to the user. These differences in Indication for Use do not raise any additional concerns of safety or effectiveness of the subject device, only add more detail to the indication for use which is already similar to the predicate.

Analysis 2:

The subject device and predicate device have differences in accuracy, measurement distance, size and weight, but the subject device has passed both the non-clinical and the clinical testing requirements of the ISO80601-2-56 and ASTM E1965-98 testing standards for infrared thermometers and therefore does not raise additional concerns of safety and effectiveness when compared with the predicate device.

Analysis 3:

The Reference Body Site and Operational, and Storage Environmental Conditions of the subject device cannot be compared to with the predicate device since these characteristics of the predicate device are not available; however, the subject device meets the requirement of safety and essential performance standard ISO 80601-2-56. These characteristics will not affect the effectiveness and safety of the subject device.

Analysis 4:

The Intended Use Environment of the subject device cannot be compared to with the predicate device since this characteristic of the predicate device is not available; however, the subject device passes IEC60601-1-2 and IEC60601-1-11 testing related to its specific usage environment and therefore does not raise any additional concerns of safety and effectiveness.

Analysis 5:

The subject device and predicate device have different Patient Contacting Materials, which could raise questions of biocompatibility; however, the materials of the subject device pass the necessary biocompatibility testing per ISO10993-5 and ISO10993-10 and the materials are shown to not affect the safety of the subject device.

Analysis 6：

The subject device has software differences in measuring interval, memory, auto power-off, and temperature ranges used for the identification of “Body Temp Lo” and “Body Temp Hi” when compared to the predicate device; however, the subject device passed the necessary performance testing and software validation which demonstrated the compliance of subject device with these specifications and these differences therefore will not affect the effectiveness and safety compared with the predicate device.

9. Non-Clinical Test Conclusion

The test results demonstrated that the subject device complies with the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests.
- ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].

- ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- IEC 60601-1-11:2015 Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

The software verification and validation were conducted in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The test results demonstrated the software function met the requirements.

10. Clinical Test Conclusion

Controlled human clinical studies were conducted on subject device with predicates in accordance with ASTM E1965-98, clinical bias, clinical uncertainty and clinical repeatability have been evaluated per clinical validation for infrared thermometer. The clinical trial results verify that the clinical accuracy of the subject device is not inferior to that of predicate device. Total 161 subjects and three age groups, including age 0~1 (40 subjects), age 1~5 (36 subjects) and age above 5 (85 subjects) are included in each clinical study, including febrile and afebrile persons. Compared statistical result of clinical bias and clinical repeatability of two comparison groups, the results of subject device meet the performance parameters claimed in user manual, and the subject device complies with ASTM E1965-98.

11. Conclusion:

Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the Infrared Thermometer (Model HT-820D) is Substantially Equivalent (SE) to the predicate device (K182597) which is US legally market device and does not raise any new safety and effectiveness issues.